K082347

510(k) Summary

as required by 807.92

NOV 1 8 2008

1. Company Identification

Konica Minolta Medical & Graphic, Inc.
No. 1 Sakura-machi, Hino-shi, Tokyo 191-8511, Japan

2. Submitter's Name and Address

Koji Matsushima (Mr.)
General Manager
Regulation Management Division
Quality Assurance Center
2970 Ishikawa-machi, Hachioji-shi, Tokyo 192-8505, Japan
Telephone: 81-42-660-9607
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3. Date of Submission

August 12, 2008

4. Device Trade Name

Digital Radiography, FlexDR C30

5. Common Name

Solid State X-ray Imager (Flat Panel / Digital Imager)

6. Classification

Class II, 21 CFR 892. 1630, Solid State X-ray Imager

7. Product Code

90 MQB

8. Predicate Device

Direct Digitizer, Regius Model 370, K051418
Canon Inc, Digital Radiography Model CXDI-40C, K031633

9. Description of Device

FlexDR C30 is comprised of a reader and an elevator stand that raises and lowers the reader.
The reader is an X-ray image reader with a built-in FPD as an X-ray detector. This reader is linked to the exposure timing of the X-ray generator and starts reading of the X-ray image immediately after exposure. The read images are stored inside, and then they are converted one by one to digital data and sent to Medical Image Working Station, CS-3000, 510(k) cleared, K051523.
The operator can manually adjust the height of the reader to match the height of the patient by holding the reader elevation handle at the rear of the reader.

10. Indications for Use

The device is intended for use for medical purpose in a hospital, etc., in order to convert X-ray image data to digital signal and to transfer the converted data to printer, filing system, image display device, etc.

11. Substantial Equivalence to Predicate Device

The Digital Radiography, FlexDR C30 is substantially equivalent to our Direct Digitizer, Regius Model 370, K051418 and Canon Inc, Digital Radiography Model CXDI-40C, K031633. Comparison of the principal characteristics is shown in Section 4.

12. Compliance Standard

Safety standard : IEC60601-1 Ed.2(1988)+ A1(1991)+A2(1995)
Electromagnetic Compatibility : IEC60601-1-2 Ed.2(2001)+A1(2004)

13. Conclusion

The Digital Radiography, FlexDR C30 has basically the same technological characteristic as the predicate devices which are approved 510(k) number: K051418 and K031633. This 510(k) has demonstrated substantial equivalence as the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Konica Minolta Medical & Graphic, Inc.
% Mr. Russell Munves
Official Correspondent
Storch, Amini & Munves, P.C.
140 East 45th Street, 25th Floor Two Grand Central Tower
NEW YORK NY 10017

AUG 23 2013

Re: K082347
Trade/Device Name: Flex DR C30
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: MQB
Dated: October 20, 2008
Received: October 22, 2008

Dear Mr. Munves:

This letter corrects our substantially equivalent letter of November 18, 2008.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known) : K082347

Device Name : Flex DR C30

Indications for Use:

The device is intended for use for medical purpose in a hospital, etc., in order to convert X-ray image data to digital signal and to transfer the converted data to printer, filing system, image display device, etc.
Flex DR C30 is not intended for use with FFDM systems.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K082347